continued treatment with conservative treatment modalities. To quantify the effects of these treatments on the quality of life, the Oswestry questionnaire (6) was administered at the time of patient enrollment into the study and during the follow-up period.

Our data suggest that the cumulative costs of SCS therapy are bimodal, with an initially high component for 2.5 years because of the requirement for expensive implantable hardware. After that period, the costs of CPT were greater than those of SCS therapy through 5 years. We made no attempt to attribute monetary values to the degree of pain relief, the benefits of a return to employment, improvements in the quality of life, or reductions in workman's compensation benefits, where applicable, because of multiple variable factors and the subjectivity that such calculations would impose. Such considerations would increase the advantages of SCS over CPT.

PATIENTS AND METHODS

Patient Selection

We have a large database that includes data for 350 patients who have undergone SCS in the past 20 years. For this study, we extracted data for consecutive patients with failed back syndrome. One hundred twenty-two patients were included in that category. All patients were initially gated through a multidisciplinary pain clinic, where conservative methods had failed. The patients were then referred for SCS therapy. While these patients were awaiting trial stimulation, 18 patients either moved or refused to participate in the study and thus were lost to follow-up monitoring. Because none of those 18 patients received further treatment of any kind, they did not incur further expense to the system. Therefore, we did not factor in anticipated costs for the purposes of this study.

These exclusions left a working group of 104 patients who were monitored for a minimum of 5 years. The data were derived from chart reviews and follow-up appointments, supplemented with telephone interviews. The patients were then subdivided into two groups, i.e., Group A (with implants, SCS group) and Group B (without implants, CPT/control group). The groups were matched with respect to age, sex, mean number of operations performed before enrollment into the study (3.3 operations), and time away from work since injury (minimum of 1 yr), and all patients were evaluated by the same multidisciplinary pain specialist group.

Group A consisted of 60 patients (57.7%; 28 female patients [47%] and 32 male patients [53%]), with a mean age of 52.3 years. After evaluations and successful trials, these patients underwent permanent SCS electrode implantation, and they continued to achieve more than 50% pain relief throughout the 5-year follow-up period. There were no explantations of the system because of loss of pain control; although four patients exhibited slight decreases in efficacy during the follow-up period, they continued to be quite comfortable and satisfied with the stimulation program.

The control group design was necessarily limited by practical considerations for human experimentation. An ideal control group would be composed of patients who were referred for SCS and responded favorably to trial stimulation but were then randomly assigned to the implant-treated group (surgical treatment, Group A) and a control group (Group B) in which the functioning electrode was removed after trial stimulation. In that event, the patients in the control group would have undergone surgical procedures specifically designed not to benefit the patients, which is an ethically intolerable situation. To maintain consistency in as many parameters as possible, including the use of a surgical procedure, our control group (medical treatment, Group B) was defined as patients who were referred for SCS but did not undergo electrode internalization. Internalization was not performed because those patients did not achieve more than 50% pain relief from their stimulators, despite stimulation-induced paresthesia covering the territory of the pain. The failure to achieve pain control may be attributable to nonspecific reasons. This control group constitutes a reasonable sample for comparisons between long-term surgically treated and conservatively treated patients with similar causes for their pain.

Group B consisted of 44 patients (42.3%; 21 female patients [48%] and 23 male patients [52%]), with a mean age of 51.4 years. This group was treated with conservative/noninterventional therapies, was matched with Group A, and was monitored every 6 months (in a manner similar to that for Group A) during the 5-year study period.

Cost Calculations

The costs tabulated in this study are actual costs based on year 2000 prices, in Canadian dollars. The costs incurred in the treatment of patients who underwent SCS were calculated under the following headings: 1) hardware used in SCS, 2) professional fees, 3) radiological investigations, 4) hospital admissions, 5) drugs, 6) nursing contacts, and 7) electrode or pulse generator replacement during the 5-year follow-up period. The costs of treatment for patients who were monitored with medical treatment were calculated in a similar manner, using the following parameters: 1) physician and other health care professional fees, 2) drugs, 3) radiological investigations (computed tomographic [CT]/magnetic resonance imaging (MRI), myelographic, and x-ray studies), 4) alternative therapies (massage, physiotherapy, and chiropractic treatments), and 5) hospital admissions for treatment of breakthrough pain.

Effects of the Canada Health Act

To non-Canadian readers, the cost calculations presented in this article may seem low, compared with their experience in the United States or western European countries. The lower financial costs are attributable to differences in pricing by the manufacturer of the implantable devices used and tight regulation (by the provincial or federal government) of the fee schedules for various professional organizations. However,

the cost comparisons between SCS and CPT are valid on a relative basis. It is important to note that, in Canada, the health care system is universal, accessible, comprehensive, portable, and publicly funded and is governed by the Canada Health Act, which was enacted in 1984 by the federal government and is administered by each province for its subjects. The Canada Health Act outlines necessary requirements that provincial health care insurance plans must fulfill. Under this act, hospitals are prohibited from adding any premium to the actual cost of any implantable device.

Costs of Implantable Devices

The costs for implantable devices were calculated from the year 2000 price list provided by the manufacturer (Medtronic of Canada, Ltd., Mississauga, ON, Canada), as charged to Canadian hospitals. We used the actual prices charged to hospitals by the manufacturer, because no increases in the prices to patients are permissible under Canadian law. The implantable devices used in SCS treatment consisted of an electrode, pulse generator, and connector cord. The pulse generator needed to be replaced after 3.5 to 4.5 years (the average lifespan of its battery). Some designs are externally powered and do not require periodic battery replacement; however, those devices have poor patient acceptance because of the inconvenience of carrying the transmitter on the belt and the use of antennae, which frequently cause skin rashes and allergic reactions. For our calculations, we observed that the frequency of pulse generator replacement was, on average, once every 4 years. Our study also revealed that the electrode required replacement once every 5 years, on average, because of fracture, migration, or fibrosis. The cost associated with electrode replacement was amortized for a 5-year period, because there was no identifiable average electrode lifespan.

Costs Associated with Iatrogenic Complications

The following iatrogenic complications were observed: 1) superficial infections that resolved with antibiotic treatment, without explantation; 2) infections that required explantation and treatment with antibiotics, followed by reimplantation; and 3) respiratory complications that required antibiotic treatment and prolonged hospital stays. In the first 1 year after implantation, we observed four infections. In two cases, the infections were superficial and resolved with intravenously administered antibiotics. The other two cases required explantation, followed by antibiotic therapy and reimplantation. Eight cases involved minor respiratory complications, such as atelectasis or pneumonia. These were treated with appropriate antibiotics as indicated, in conjunction with respiratory therapy.

Medical Personnel Costs

Physicians and other health care professionals in Canada are paid on a fee-for-service basis. The fee schedules for various professional bodies are controlled by the provincial governments, after negotiation with the professional licensing bodies. The fees paid to the various physicians and surgeons in the study were derived from the year 2000 payment schedule for the Saskatchewan Medical Association.

Nursing and Allied Health Care Professional Costs

The costs of nursing contacts for the maintenance of patients enrolled in the SCS group were derived from the hourly wages paid to the health care workers, as determined by the nursing union contract. Each patient contact was equated to 1 hour of wage. A similar approach was used for social worker involvement. The costs of physiotherapy, chiropractic treatment, massage therapy, and acupuncture were determined on the basis of the fee schedules approved by the respective associations.

Costs of Investigations

The costs of various imaging procedures (CT, MRI, myelographic, and x-ray studies) were provided by the finance department of the Regina Health District.

Hospitalization Costs

The daily hospitalization cost, as approved for the institution at which the study was conducted, was $627. This was the exact amount paid to the hospital by the government of Saskatchewan in the year 2000. No markup is chargeable to patients, according to Canadian law.

Pharmacotherapy Costs

The pharmacotherapy costs that the patients paid for pain management were determined by using the Saskatchewan Health Formulary (*Table 1*). The drugs commonly used by patients in our series included antidepressants, benzodiazepines, opioids, nonsteroidal anti-inflammatory drugs, analgesics, and muscle relaxants. These costs were determined on a monthly basis, allowing a prefixed, government-approved, pharmacy markup schedule (over wholesale prices) and a flat rate for dispensing (*Table 1*), according to the current pharmaceutical standards of practice. In our province, the government approves the wholesale price of each drug, the allowable markup for each drug, and the chargeable dispensing fees.

TABLE 1. Formulae used in the calculation of costs for pharmacotherapy[a]

A. Wholesale cost of a particular medication/mo = wholesale cost of medication/pill × number of pills consumed/patient/d × 30 d/mo

B. Pharmacy markup schedule (over wholesale cost)

$0–6.31, 30% markup

$6.32–15.81, 15% markup

$15.81–200.00, 10% markup

C. Dispensing fee for each drug for 1-mo supply = $7.15

[a] Total cost/mo/medication = Cost A + Cost B + Cost C.

Cumulative Cost Calculations

Group A

The actual cumulative costs were determined via data collection under the following headings (*Tables* 2 and 3): 1) professional costs (medical consultation fees and surgical costs); 2) costs of various imaging investigations; 3) costs of implantable equipment (electrode, pulse generator, and in-line connector); 4) costs of treatment of iatrogenic complications (infections); 5) costs of pharmacotherapy to control breakthrough pain; 6) hospital admission costs for implantation, if needed; 7) SCS maintenance costs, calculated by adding fees associated with physician contacts, nursing contacts, electrode changes because of fracture, malfunction, or shifting (with the associated professional costs and hospital charges for treatment of the pathological condition), and pulse generator changes (with the associated professional costs and hospital charges); and 8) physician contact costs (statistical analysis for our series revealed that patients with functional implants visited a family physician four times/yr and a neurosurgeon twice/yr). After we determined the yearly costs, we extrapolated the cumulative costs for a period of 5 years (*Tables 2–4*).

TABLE 2. Evaluation and implantation cost[a]

	Unit cost ($)	Average unit frequency (d)	Average unit cost ($)	Average cost/patient ($)
Consultation				
Psychiatrist	108			
Social worker	84			
General practitioner	44			426
Neurosurgeon	57			
Neurologist	85			
Orthopedic surgeon	48			
Investigations				
CT scans	465	1.7	822	
MRI scans	1045	1.1	1184	2390
X-rays	36	5.6	202	
Myelograms	135	1.4	182	
Surgery				
Anesthesia				
Implantation	192			
Internalization	93			
Neurosurgical professional fees				1156
Implantation	593			
Internalization	216			
Assistant surgeon	62			
Pulse generators				
Itrel III	5825			
Itrel II	5675			6110
X-trel	7650			
Electrodes				
Resume	1595			1595
Pisces-Quad	1595			
In-line connector	625			625
Complications				
Explantation	236	2	472	
IV antibiotic treatment	56	2	112	308
Reimplantation	8617	2	17,234	
Respiratory complications	153	4	612	
Antibiotics for superficial infections	14	2	28	
Hospital admission	627	6.9		4326
Total				16,936

[a] CT, computed tomographic; MRI, magnetic resonance imaging; IV, intravenous.

Group B

The actual cumulative costs were determined via data collection under the following headings (*Table 5*): 1) costs of evaluations by various health care professionals, including family physicians, orthopedic surgeons, psychiatrists, social workers, neurologists, and neurosurgeons; 2) imaging costs (CT, MRI, x-ray, and myelographic studies) required initially and during episodes of pain flare-up (in our series, it was observed that patients required one CT study and one MRI study every 2 yr); 3) pharmacotherapy costs, calculated as outlined for Group A; 4) costs of alternative therapies (physiotherapy, chiropractic treatments, massage therapy, and acupuncture); and 5) costs of intermittent hospitalization for treatment of acute breakthrough pain (in this series we observed that patients experiencing breakthrough pain required an average of 3 d of hospitalization/yr). It should be noted that surgical costs, including the costs of hardware for trial stimulation and hospital charges for that time, were not included for Group B.

Evaluation of Quality of Life and Patient Satisfaction

To determine the effects of SCS treatment on the quality of life and function, we administered the Oswestry disability questionnaire (6) at the time of enrollment into the study and every 1 year during the follow-up period. The results were then averaged for a 5-year period. With a separate questionnaire, patients who underwent SCS were questioned regarding their satisfaction with the treatment, whether they would undergo a repeat procedure for the same degree of benefit, and whether they would recommend this procedure to their friends and relatives with similar pain problems.

RESULTS

Group A

Sixty patients were included in Group A. Calculations of the average initial costs of implantation for the patients who received permanent SCS implants are summarized in *Table* 2.

TABLE 3. Costs of spinal cord stimulation maintenance

Description	Unit cost ($)	Unit (frequency)	Cost ($)	5-yr cost ($)
Physician contacts				
Family physician	44	4 visits/yr	176	
Neurosurgeon	57	2 visits/yr	114	
Total			290	1450
Nursing contacts for stimulation parameter optimization and counseling	30	3.1 visits/yr	92	460
Pharmacotherapy for pain flare-ups	302			1510
Electrode change[a]	1595	1	1595	1595
Professional costs for electrode change[a]				
Anesthesia	93			
Neurosurgeon	275			
Hospital charge	75			
Total	443			443
Pulse generator replacement[b]	6005	1		6005
Professional fees for pulse generator change[b]				
Anesthesia	284			
General practitioner consultation	44			
Neurosurgeon consultation	57			
Neurosurgeon	202			
Assistant surgeon	62			
Hospital charge	75			
Total	724			724
Total (5-yr cost)				12,187

[a] Once in every 5-year period.
[b] Once in every 4-year period.

TABLE 4. Costs of treating a patient with chronic pain with stimulation for 5 years

Data	Costs ($)
Table 2	16,936
Table 3	12,187
Total (*Table 2* + *Table 3*)	29,123

The types of pulse generators used in this study included Itrel II, Itrel III, and X-trel (Medtronic, Inc., Minneapolis, MN). Thirty-nine patients (65%) received Itrel II pulse generators, 14 (23%) received Itrel III pulse generators, and 7 (12%) received X-trel pulse generators. The average pulse generator cost was $6110. The electrodes used in this series were either Resume or Pisces-Quad electrodes (Medtronic, Inc.), with an average price of $1595. The average cost for the in-line connectors was $625. The initial imaging costs (before implantation) for x-rays, myelograms without CT scans, CT scans, and MRI scans of the lumbar spine were $202, $182, $822, and $1184, respectively, totaling $2390. Professional costs, which included costs for initial assessments by a primary care physician and consultation services rendered by an orthopedic surgeon, psychiatrist, social worker, neurologist, and neurosurgeon, totaled $426. The costs of surgery and anesthesia for implantation were $1156 for each implantation procedure. The average cost for treatment of iatrogenic complications was $308. The hospital charges during the study period were $627/d, with an average hospital stay of 6.9 d/patient, totaling $4326. These costs totaled $16,936/patient in the year of implantation (*Table 2*).

Maintenance costs included costs for follow-up monitoring by a family physician, a neurosurgeon, and a neuromodulation nurse and the costs of medications used during flare-up periods (*Table 3*). Patients with functional implants visited their family physicians four times/yr and a neurosurgeon twice/yr, at a total cost of $290/yr. Neuromodulation nursing contact costs for implant maintenance (optimization of stimulator parameters) were $92/yr/patient; an average of 3.1 contacts/yr were required. The cost of medications for the treatment of breakthrough pain was $302/yr. Our records

TABLE 5. Annual medical resource use by patients who have undergone nonsurgical chronic care[a]

Therapy description	Unit cost ($)	Average unit (frequency)	Cost/yr ($)	5-yr cost ($)
Physician visits (24 visits/yr with family physician)	22	24	528	2640
Specialist consultation				
1 visit with neurologist	85	1	85	425
1 visit with neurosurgeon	57	1	57	285
1 visit with orthopedic surgeon	48	1	48	240
1 visit with psychiatrist/psychologist	108	1	108	540
Social worker	21	4 h	84	420
Hospitalization for breakthrough pain	627	3 d	1881	9405
Medications (antidepressants, anti-inflammatory agents, benzodiazepines, muscle relaxants, opioids)[b]	861		861	4305
Alternative therapies				
Physiotherapy	30	57.6	1736	8680
Chiropractic treatment	22	17.2	373	1865
Massage therapy	40	10.1	404	2020
Acupuncture	35	10.6	371	1855
Total for alternative therapies			2884	14,420
Total maintenance cost (Cost A + Cost B + Cost C + Cost D + Cost E)				6536
Initial diagnostic procedures[c]				
CT scans, lumbar spine	465	1.8	825	825
MRI scans, lumbar spine	1045	1.0	1071	1071
X-rays, lumbar spine	36	6.8	244	244
Myelograms	135	1.4	189	189
Total for diagnostic procedures			2329	2329
Total			8865	35,009
Diagnostic procedures precipitated by flare-ups during study, CT and MRI scans, lumbar spine[d]	1510	2	3020	3020
Total (5-yr)				38,029

[a] CT, computed tomographic; MRI, magnetic resonance imaging.
[b] Derived from chart review.
[c] For establishing diagnosis and entry into the study.
[d] Performed once every 2 years.

revealed that SCS patients required, on average, one electrode change during the 5-year study period (precipitated by fracture, shifting, or nonfunction); the associated costs of surgery for replacement were $2038 (cost of the electrode [$1595] + professional costs [$368] + hospital costs [$75]). The pulse generator also needed to be replaced an average of once every 4 years, at a cost of $6729, because of battery power depletion.

To determine the cumulative costs, we projected these calculations for a 5-year period by determining the following average costs per patient per year (*Tables* 2 and 3): Cost a, costs of the initial evaluation ($426) and investigations ($2390); Cost b, cost of implantation ($13,812; hardware costs, $8330; surgical fees, $1156; hospitalization costs, $4326); Cost c, cost of treatment of iatrogenic complications ($308); Cost d, SCS maintenance cost ($684; physician, $290; nursing contacts, $92; drugs, $302); Cost e, cost of electrode replacement (once every 5 yr) ($2038; for purposes of calculation, this was amortized for a 5-yr period at $408/yr); Cost f, cost of pulse generator replacement (once every 4 yr) ($6729; pulse generator, $6005; surgical fees, $649; hospital costs, $75). Therefore, the cumulative costs were as follows (*Table 6*): Year 1, Cost a + Cost b + Cost c + amortized Cost d; Year 2, Year 1 cost + Cost c + amortized Cost d; Year 3, Year 2 cost + Cost c + amortized Cost d; Year 4, Year 3 cost + Cost c + amortized Costs d + e;

TABLE 6. Actual annual costs of spinal cord stimulation and conventional pain therapy for 5 years[a]

Year	Actual costs ($)		Cumulative costs ($)	
	SCS	CPT	SCS	CPT
1	18,028	8865	18,013	8865
2	1092	7291	19,120	16,156
3	1092	7291	20,212	23,447
4	7819	7291	28,013	38,738
5	1092	7291	29,123	38,029
Total	29,123	38,029		
Average	5825	7606		

[a] SCS, spinal cord stimulation; CPT, conventional pain therapy.

Year 5, Year 4 cost + Cost c + amortized Cost d. At the end of a 5-year period, the average cumulative cost for this group was $29,123.

During the 5-year study period, none of these patients underwent lumbar spine surgery. Therefore, no extra costs were attributable to such procedures.

Group B

The control group consisted of 44 patients. This group required a greater number of physician visits per year for assessments, as well as to obtain prescriptions for pharmacotherapy or referrals to allied health care professionals. The average number of family physician visits was 24/patient/yr, with an average yearly cost of $528. In addition, each patient sought consultations with various specialists (a neurosurgeon, an orthopedic surgeon, a neurologist, a psychiatrist/psychologist, and a social worker) an average of five times/yr, with a cost of $910/yr. On average, each patient initially required 1.8 CT scans, 1.0 MRI scan, 6.8 x-rays of the lumbar spine, and 1.4 myelograms. Therefore, the average initial imaging costs for this group were $2329. In addition, during the follow-up period, each patient required CT/MRI studies once every 2 years, on average, with a cost of $1510. This group also required hospitalization an average of 3 d/yr, because of acute pain exacerbations, at a cost of $1881. The cost of pharmacotherapy for pain averaged $861/yr (*Table 5*). The average numbers of visits to physiotherapists, chiropractors, massage therapists, and acupuncturists were 57.6, 17.2, 10.1, and 10.6 visits/yr, respectively, yielding a total cost of $2884/patient/yr.

To determine the cumulative costs, we projected these calculations for a 5-year period by determining the following average costs per patient per year (*Table 5*): Cost a, cost of investigations ($2329); Cost b, cost of maintenance (total, $6536; pharmacotherapy, $861; physician contacts, $910; alternative therapies, $2884; hospitalization for treatment of breakthrough pain, $1881); Cost c, cost of secondary investigations every 2 years (costs of CT and MRI scans, $1510 × 2 = $3020, amortized for a 4-yr period as $755/yr, allocated to the second, third, fourth, and fifth years of the follow-up period). Therefore, the cumulative costs per patient for Group B were as follows (*Table 6*): Year 1, Cost a + Cost b; Year 2, Year 1 cost + Cost b + amortized Cost c; Year 3, Year 2 cost + Cost b + amortized Cost c; Year 4, Year 3 cost + Cost b + amortized Cost c; Year 5, Year 4 cost + Cost b + amortized Cost c. At the end of a 5-year period, the cumulative costs for this group were $38,029/patient.

Figure 1 demonstrates that the costs of SCS therapy are greater than those of CPT in the first 2.5 years, because of the initial high costs of the implantable devices. After that period, SCS treatment becomes economically favorable for patients who respond positively to SCS. Although the costs of pulse generator replacement in the fourth year tend to bring the two curves closer, CPT remains relatively more expensive. With projection of these data for a 10-year period, these savings are magnified (*Fig. 2*).

Quality of Life Considerations

Although the cost of therapy may dictate which methods are used for the treatment of chronic pain, patient quality of life is equally important, if not more important. Patient functioning and quality of life were measured by using the Oswestry disability questionnaire (6). The questionnaire indicated a 27% improvement in quality of life for the SCS group, compared with 12% improvement for the control group.

For assessment of patient satisfaction with SCS, an additional questionnaire was used. The responses were graded into three groups, i.e., very satisfied, satisfied, and unsure. Thirty-six patients (60%) reported being very satisfied, 17 patients (28%) reported being satisfied, and 7 patients (12%) were unsure. Because SCS was the only modality that had given the very satisfied and satisfied groups comfort and allowed reductions of drug usage, the patients noted that they

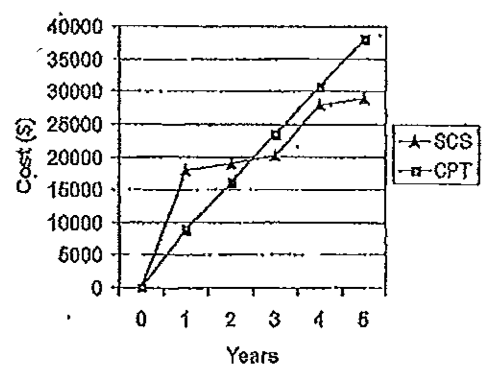

FIGURE 1. *Graph illustrating the cumulative costs of SCS versus CPT for a 5-year period. The 2.5-year payoff period should be noted.*

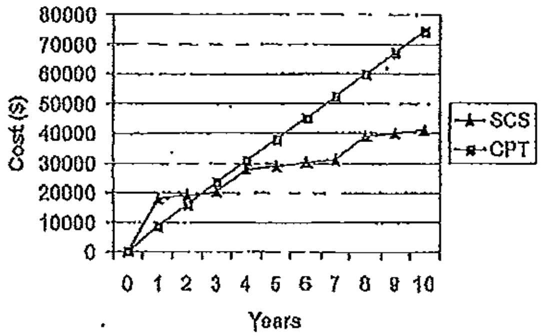

FIGURE 2. *Graph illustrating the cumulative costs of SCS versus CPT projected for a 10-year period.*

would recommend this procedure to relatives or friends with similar pain problems.

A benefit of SCS treatment in addition to the cost savings was that nine patients (15%) in Group A were able to return to some form of gainful employment, compared with none in Group B. Drug intake was also reduced with SCS. Preoperatively, the average cost for drug therapy for pain was $78/mo (this cost was calculated from our patient records before enrollment and is not presented in the tables); postoperatively, the cost decreased to $25/mo. The average pharmacotherapy cost for the control group was higher, i.e., $861/yr ($72/mo).

Statistical Analyses

The actual yearly costs for SCS and CPT for the 5-year period are summarized in *Table 6* and *Figure 3*, which indicate that the average yearly costs for SCS are less than the mean yearly costs for CPT. In an effort to provide realistic costs to hospital administrators for budgeting, we added a net present value of 5% (inflation factor) to the actual costs; these adjusted costs are presented in *Table 7*. Once again, the mean CPT costs are much higher than the mean SCS costs.

We observed that, in *Tables 6* and *7*, the Year 1 cost for SCS therapy ($18,028) is much higher than the costs for the remaining years, particularly Years 2, 3, and 5. This observation may affect analysis of the data and may represent an outlying point in the data set. To provide a reasonable analysis, we redistributed some of the cost from Year 1 to Years 2, 3, and 5. *Table 8* and *Figure 4* present the adjusted costs. We transferred $9000 from Year 1 and added $3000 to each of Years 2, 3, and 5. Importantly, this transfer had no effect on the total or mean costs. It can be observed in *Tables 7* and *8* that the mean yearly costs remained the same, at $6170.32. Therefore, we used the data in *Table 8* for further analysis.

We claim that the mean yearly cost of CPT is higher than the mean yearly cost of SCS. A statistical hypothesis-testing procedure was used to examine this conjecture. In this case, the null hypothesis (H_0) was that the average costs for the two procedures were the same. The research or alternative hypothesis (H_a) was that the mean annual SCS costs were less than the CPT costs. In other words, the null and alternative hypoth-

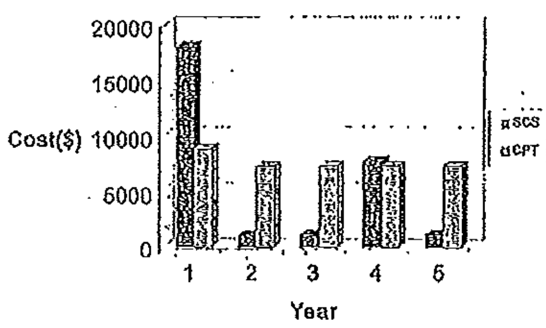

FIGURE 3. *Bar graph illustrating the yearly noncumulative costs of SCS versus CPT for a 5-year period.*

TABLE 7. Inflation-adjusted annual costs of spinal cord stimulation and conventional pain therapy for 5 years (including 5% inflation)[a]

Year	SCS cost ($)	CPT cost ($)
1	18,028.00	8865.00
2	1147.99	7664.81
3	1206.88	8057.80
4	9134.94	8470.93
5	1333.77	8905.24
Total	30,851.58	41,963.78
Average	6170.32	8393.00

[a] SCS, spinal cord stimulation; CPT, conventional pain therapy.

TABLE 8. Redistributed adjusted annual costs of spinal cord stimulation and conventional pain therapy for 5 years (including 5% inflation)[a]

Year	SCS cost ($)	CPT cost ($)
1	9028.00	8865.00
2	4147.99	7664.81
3	4206.88	8057.80
4	9134.94	8470.93
5	4333.77	8905.24
Total	30,851.58	41,963.70
Average	6170.32	8393.00

[a] SCS, spinal cord stimulation; CPT, conventional pain therapy.

eses are as follows: H_0, there is no difference between the mean costs of the two treatment modalities; H_A, the mean cost of SCS is less than the mean cost of CPT.

The hypothesis test for comparing two population means was investigated with the pooled, two-sample, Student's t test. First, we assumed that the population variances were equal. The analysis was performed by using Minitab statistical software (Minitab, Inc., State College, PA), which formulated a P value of 0.04. This provided evidence of a significant difference between the average treatment costs for SCS and CPT procedures. It should be noted that the pooled t procedures assumed that the population variances were homogeneous. We also performed analysis with unequal population variances; in that situation, the P value was 0.58, and thus we reject the null hypothesis of equality of the mean costs at a 5.8% level of significance. In both cases, we reject the null hypothesis. There is sufficient evidence to conclude that the mean yearly cost of SCS is less than the mean yearly cost of CPT. SCS is thus cost-effective, compared with CPT, for the 5-year period. From *Tables 6* and *8*, it can be safely extrapolated that the mean treatment cost for SCS will continue to be significantly smaller than the average treatment cost for CPT as the number of years increases.

Sensitivity Analysis

In this study, we tabulated data from actual patient files, for patients monitored within a constant delivery environment. There are three possible variables that must be considered, i.e., 1) the clinical efficacy rate for SCS, 2) the complication rate associated with SCS, and 3) the lifespans of the pulse generator battery and the electrode.

These variables are less applicable in our case than in other published studies, in which theoretical models of medical resource utilization were used. The clinical efficacy rate has remained stable for the past 10 years but may improve in the future, with the development of more effective patient screening. In our study, no operative procedures were required, except for those related to hardware complications. This incidence has remained constant in all published studies in the past decade, leaving only two variables that may affect costs in the foreseeable future, namely the lifespan of the electrode and the battery life of the pulse generator. The manufacturers are actively pursing improvement of these items. If the manufacturers were to improve the function of these two components by 25% in the future, the payoff period would decrease from 2.5 years to 2.3 years.

DISCUSSION

Shealy et al. (22, 23) were the first to advocate the application of electrical current to the spinal cord to relieve pain. The physiological mechanism by which SCS relieves pain is partially explained by the gate theory proposed by Melzack and Wall (18). In early years, many patients with chronic pain underwent SCS; however, because the selection criteria were poorly defined, the results were far from satisfactory (7). In subsequent years, indications were clarified by the work of Lazorthes et al. (16), Winkelmuller (25), Gybels et al. (8), Kim et al. (10), North et al. (20, 21), Kumar et al. (14), Meglio et al. (17), and Barolat et al. (1), and SCS has become an important mode of treatment for failed back syndrome. We attempted to match the two groups with respect to the cause of their pain as much as possible. However, Group B could have a slightly higher proportion of patients with nociceptive pain and Group A patients with lumbosacral rhizopathy. With the increasing costs of medical technology, it is necessary for physicians to provide evidence that SCS is a cost-effective method of treatment, compared with nonsurgical therapies.

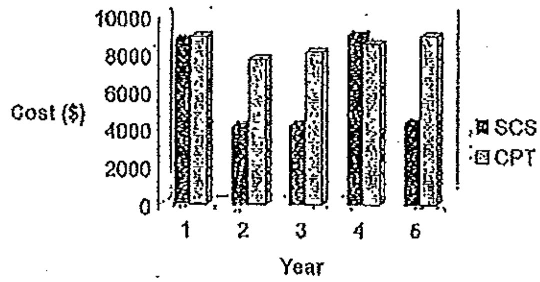

FIGURE 4. *Bar graph illustrating the redistributed adjusted costs of SCS versus CPT for a 5-year period, including 5% inflation.*

To date, there have been only two published studies (2, 3) on the cost-effectiveness of SCS, to our knowledge. Bell et al. (3) demonstrated that, among patients who responded favorably to SCS, the estimated payoff period was 2.1 years. However, in that study, Bell et al. (3) developed theoretical models of medical resource utilization for the two groups of patients (SCS and CPT). Their cost calculations were based on the anticipated use of resources, as determined from clinical literature, retrospective data sets, expert opinions, and published diagnostic and therapeutic protocols. The drawback of that study was that all calculations were based on presumptions, rather than actual recorded costs for the treatment of the two groups. Bel and Bauer (2) monitored 14 patients for the relatively short period of 2 years and concluded that the treatment of chronic pain with SCS was cost-effective, compared with conventional therapy, because the cost of electrode implantation was quickly compensated for by a drastic reduction in drug utilization and increased reentry into the workforce after surgery. That study was limited because of the small number of patients and the short follow-up period, and it failed to provide data for calculation of the recovery period for the high costs of implantable devices used in SCS treatment, compared with CPT.

We designed our study to allow monitoring of a large number of patients in the two groups (SCS and CPT) for a 5-year period and to address some of the flaws in those earlier reports. We recorded the actual costs incurred in the treatment of both groups of patients, increasing the validity of our results. The absolute derived costs may not be directly com-

parable to those encountered and may be lower than those in the United States or Europe. This difference is a consequence of the nature of the medical delivery system in Canada and differences in pricing by the manufacturer in different countries, which limit absolute costs. Because the same economic scale was applied to the various factors that modulate therapy for both of our study groups, our conclusions remain valid on a relative basis.

The cumulative cost for the SCS group for the 5-year period was $29,123/patient (*Table 4*), compared with the control group figure of $38,029/patient (*Table 5*). The higher costs for the non-surgically treated group are attributable to the patients' greater utilization of health care resources for drug therapy, rehabilitation services, and other therapies for pain control (*Table 5*). *Figure 1* indicates that the costs of CPT exceed those of SCS, on a monthly basis, at 2.5 years. In the SCS group, costs are higher in the first 2 years because of the high costs of the implantable devices. After 2.5 years, the costs of primary treatment with SCS become less than those for the control group. This cost benefit is maintained throughout therapy, despite the periodic increases in expenses attributable to the costs associated with hardware manipulation and replacement of the pulse generator (because of depletion of its battery power) (*Fig. 1*).

Our analysis indicates that additional cost savings could result from improvements in the effectiveness of SCS therapy. These improvements might be achieved via more effective patient selection criteria and technological advances in the equipment used. The manufacturers need to focus on methods to improve the longevity of the pulse generator and the durability of the electrode.

CONCLUSIONS

Patients with chronic pain secondary to failed back syndrome who respond to SCS therapy can achieve significant cost savings, compared with a control group. Additional benefits may include an increased rate of work rehabilitation, increased pain control, and a better quality of life. A coordinated approach to the treatment of this disabling ailment can result in better utilization of scarce health care funds.

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COMMENTS

Kumar et al. presented two groups of patients treated by spinal cord stimulation (SCS) and conventional chronic pain therapy (CPT), respectively. They compare the cost-effectiveness of both treatments. In the age of science and technology, these types of cooperative studies are very important in evaluating the real value of surgical methods, which usually seem very expensive. In the presented series, SCS is

shown as not only an effective method but also a cost-effective treatment in comparison with CPT. The most important benefit of SCS was that 15% of the patients went back to work after treatment. Improvement in quality of life was 27% in this group, as compared with 12% in the control group, in which no patient returned to work. Drug intake was also reduced in the SCS group, which is the most important finding of this study. It must be kept in mind that the results of this study reflect the skills of an experienced medical team; another, less experienced group would not necessarily achieve the same results.

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Kumar et al. of the University of Saskatchewan present a study of the cost-effectiveness of SCS as compared with CPT. Sixty patients underwent SCS, and 44 patients in whom a trial of SCS had failed were the controls. These patients were followed for a 5-year period, and actual costs incurred for diagnostic imaging; professional fees paid to physicians; implantation costs, including hardware; nursing visits for the maintenance of the stimulators; physiotherapy; chiropractic; massage therapy, and hospitalization costs for breakthrough pain, were all calculated. In addition, the authors analyzed outcomes based on the Oswestry questionnaire (2) to estimate the effect of treatment on quality of life. On the basis of this analysis, Kumar et al. conclude that the cumulative mean cost of SCS therapy during a 5-year period was $29,122 per patient, as compared with $38,029 per patient for CPT. Extrapolating the cost savings for an additional 5 years on the basis of these data, the authors predict that the cost savings would be even greater.

A number of aspects of this study merit comment. First, the cost of Canadian health care in comparison with that of the United States is a relative bargain in that fees and profits are statutorily limited. Even taking into account the relative inflation of the Canadian dollar in comparison with the U.S. dollar, I think that the actual dollar savings in the United States might be even greater than the savings projected in this study. Nevertheless, the cost analysis is performed within a system that is quite scrupulous about cost accounting.

This type of study is difficult to conduct in any environment. One can certainly quibble about the nature of the "control group." The study was not performed in a group of patients who would otherwise have gone forward with SCS on the basis of a successful trial, which would constitute the authors' "ideal" study, in which patients would be randomized to either SCS or CPT. As the authors point out, this type of randomized study would present some ethical problems. Whether these difficulties can be surmounted in a future study remains to be seen. Nevertheless, the control group (Group B) in this study represents a group in whom an SCS trial had failed and, for that reason, may represent a more difficult category of patient. Potentially, Group B's treatment would seem more expensive than that of the patients who underwent SCS (Group A), regardless of the therapy implemented.

Perhaps most striking is the similarity of the results of this study to those reported by Bell et al. (1). That study also found that the financial breakeven point for SCS was approximately 2 years, as compared with more conservative management. It also found that at 5 years, SCS had a distinct cost-effectiveness advantage over nonsurgical management. The difference between these two studies is that the analysis of Bell et al. was based in part on cost projections, whereas Kumar et al.'s data represent actual costs. That the results of these two studies, which were performed in two different countries under different circumstances, are in such close agreement suggests to me that there is an important principle at work: namely, that SCS does result in health care system cost savings that are realized only after several years. It may well be that a more rigorous Class I outcome study of SCS in comparison with conservative management will be performed. Until that time, this study by Kumar et al. should be considered the benchmark work.

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Financial impact of spinal cord stimulation on the healthcare budget: a comparative analysis of costs in Canada and the United States

Clinical article

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Object. Many institutions with spinal cord stimulation (SCS) programs fail to realize that besides the initial implantation cost, budgetary allocation must be made to address annual maintenance costs as well as complications as they arise. Complications remain the major contributing factor to the overall expense of SCS. The authors present a formula that, when applied, provides a realistic representation of the actual costs necessary to implant and maintain SCS systems in Canada and the US.

Methods. The authors performed a retrospective analysis of 197 cases involving SCS (161 implanted and 36 failed trial stimulations) between 1995 and 2006. The cost of patient workup, initial implantation, annual maintenance, and resources necessary to resolve complications were assessed for each case and a unit cost applied. The total cost allocated for each case was determined by summing across healthcare resource headings. Using the same parameters, the unit cost was calculated in both Canadian (CAD) and US dollars (USD) at 2007 prices.

Results. The cost of implanting a SCS system in Canada is $21,595 (CAD), in US Medicare $32,882 (USD), and in US Blue Cross Blue Shield (BCBS) $57,896 (USD). The annual maintenance cost of an uncomplicated case in Canada is $3539 (CAD), in US Medicare $5071 (USD), and in BCBS $7277 (USD). The mean cost of a complication was $5191 in Canada (range $136–18,837 [CAD]). In comparison, in the US the figures were $9649 (range $381–28,495) for Medicare and $21,390 (range $573–54,547) for BCBS (both USD). Using these calculations a formula was derived as follows: the annual maintenance cost (a) was added to the average annual cost per complication per patient implanted (b); the sum was then divided by the implantation cost (c); and the result was multiplied by 100 to obtain a percentage ($a + b \div c \times 100$). To make this budgetary cap universally applicable, the results from the application of the formula were averaged, resulting in an 18% premium.

Conclusions. For budgeting purposes the institution should first calculate the initial implantation costs that then can be "grossed up" by 18% per annum. This amount of 18% should be in addition to the implantation costs for the individual institution for new patients, as well as for each actively managed patient. This resulting amount will cover the costs associated with annual maintenance and complications for every actively managed patient. As the initial cost of implantation in any country reflects their current economics, the formula provided will be applicable to all implanters and policy makers alike. *(DOI: 10.3171/2009.2.SPINE0865)*

Key Words • spinal cord stimulation • financial impact • healthcare budget

Pain is a major driving force for a patient to seek medical attention. The anatomy and physiology of chronic pain remain a subject of continued exploration and research. By proposing the gate theory, Melzak and Wall[15] stimulated new interest in pain research and therapy. Spinal cord stimulation has become an established modality in the treatment of chronic neuropathic pain since its introduction in 1967 by Shealy and colleagues.[18] There is substantial evidence in the literature demonstrating the efficacy of SCS in the management of chronic pain[8,10–12,16,17,20,24] and also its cost-effectiveness.[1,6,9,19,21] This has resulted in widespread application of this treatment throughout the world. It is estimated that ~ 35,000 SCS systems were sold worldwide last year, and this number is rising.

Most of those who implant an SCS system only take into consideration the initial cost of implantation and fail to make any budgetary allocation for annual maintenance and complication costs. The cost of treating complications is a variable burden. The mean rate of complications has been quoted by several authors to be ~ 35%.[3,11,13,22,23] With the rising cost of healthcare, there is

Abbreviations used in this paper: BCBS = Blue Cross Blue Shield; CAD = Canadian dollar; IPG = implanted pulse generator; SCS = spinal cord stimulation; USD = U

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increased demand by third-party payers for physicians to demonstrate the cost-effectiveness of the treatment plan and thus be accountable for financial resource allocation.

The primary object of this paper is to provide a realistic estimate of the global cost per patient that an institution assumes when it accepts a patient in whom a spinal cord stimulator is required. The secondary objective is to propose a formula that ties the initial implantation costs to annual maintenance and complication costs per patient. This formula will be useful to health institutions worldwide in their healthcare budget allocation.

To fulfill these objectives, we retrospectively analyzed our database of 197 patients, of whom 161 have undergone implantation of an SCS system over the past 12 years. We calculated the cost of the initial workup, implantation, annual maintenance, and the mean annual cost of complications per patient implanted during this period. Statistical analysis of the data was instrumental in formulating the relationship between the initial implantation cost and the added expense of annual maintenance and complications. Using the same parameters, a comparative analysis of health resource utilization cost in the US was performed. All calculations were done using 2007 prices, and it should be noted at the time of writing that the CAD and USD are almost of equal value. This study will provide a realistic estimate of the global cost per patient that an institution assumes in either Canada or the United States.

Methods

Patient Population

Our institution has been collecting data on patients who have undergone a spinal cord implantation for chronic benign pain syndrome over the past 25 years (1982–2006; mean follow-up 98.3 months). To produce meaningful data relevant to achieving the objectives of this study, we conducted an in-depth retrospective analysis of 197 consecutive patients (108 men and 89 women, mean age 52 years [range 20–87 years]), of whom 161 underwent implantation over the past 12 years (1995–2006). This timeframe was chosen because recent advancements in technology and methodology have tended to improve the long-term results and reduce complication rates compared with the previous decade. The follow-up examination was performed at 6-month intervals for the first 3 years and annually thereafter. Six patients died of unrelated causes during the follow-up period and 9 patients were lost to follow-up, yielding an effective follow-up rate of 92%.

The analysis was done to determine: 1) the average cost of implantation per patient, including the preoperative evaluation and the trial; 2) the annual cost to maintain an SCS system; 3) the average cost per complication; and 4) the average annual cost of complications per patient. Using the same parameters, a comparative analysis of the cost was conducted using the US payment systems.

Costing Approach

Resource information was obtained from the finance department of the Regina Qu'Appelle Health Authority, which is the governing body of our institution. As this study was conducted in Regina, Saskatchewan, Canada, all costs references are taken from that province's fee schedule for the year 2007. The costs of equipment or its replacement were obtained from the manufacturer's price list for the year 2007 (Medtronic, Inc. and Boston Scientific Neurological). By Canadian law the hospitals are not permitted to mark up these products.

The physicians are paid on a fee-for-service basis in accordance with the 2007 provincial fee schedule. Costs associated with other health professionals (that is, nurses and technicians) are calculated according to the hourly wage earned. The frequency of imaging procedures was extracted from the patients' charts. The cost of each imaging procedure was derived from the hospital payment schedule. The Regina General Hospital, where this study was conducted, was reimbursed at the rate of $1365.00/patient/day by the government of Saskatchewan for the year 2007. We have used this figure to calculate the cost of the length of stay. Similarly, the day surgery or ambulatory care charges were based on the actual reimbursement by the government to the hospital. The charge for ambulatory care is a composite fee to cover the use of the facility, personnel, and procedure undertaken at that visit.

The most commonly used drugs for treatment of complications were analgesics, including opioids, and antibiotics. The cost of pharmacotherapy for each patient was calculated according to the Saskatchewan Health Formulary. The system allows a predetermined government-approved mark-up schedule and a flat rate for dispensing according to pharmaceutical standards.

Implantation and Annual Maintenance Costs

The costs incurred to implant and maintain an SCS system were calculated under the following headings: 1) hardware used in SCS, 2) professional fees, 3) radiological investigations, 4) hospital admissions, 5) drugs, 6) nursing contacts, and 7) nonrechargeable pulse generator replacement cost (amortized over 4 years).

The level of healthcare utilization for each heading was obtained for an average patient and a unit cost applied (for detailed calculations refer to *Appendix 1*).

Complication Cost

Healthcare costs are governed by the time course needed to reverse the effect of the complication, the type of corrective treatment rendered, the need and duration of hospitalization, drug therapy, professional time, and hardware costs.

For each category of complication, the healthcare resource utilization was assessed for the individual patient using the aforementioned headings. To obtain the average cost per complication, the total cost of all complications over the 12-year period was divided by the total number of complications that occurred over that time. Furthermore, to determine the mean annual cost of complication per SCS-treated patient, the total cost of all complications over the study period was divided by the number of patients in whom stimulators were implanted and then

divided by the average duration of follow-up. Given the wide variation in the cost of different complications, results are presented as the mean (Table 1).

Cost Comparison With the US

To provide a clear understanding of the financial impact for implanters in the US, we are providing a parallel analysis of our frequency data, using the payment schedule of 2 major insuring agencies in the US, namely Medicare and BCBS. We have chosen the payment schedule from the state of Texas, as it most closely approximates the mean payments for the country. We have also assessed the comparative average cost of implantation per patient, cost of yearly maintenance, and the relative cost increase when a complication occurs.

Financial Impact

The annual budget is arrived at by adding the initial implantation cost, the cost associated with annual maintenance, and the treatment cost of complications per patient implanted. This process can be simplified by adopting the following formula: the annual maintenance cost (a) was added to the average annual cost per complication per patient implanted (b); the total was divided by the implantation cost (c); and the result was multiplied by 100 to obtain a percentage ($a + b \div c \times 100$). This formula will provide the "grossed-up" value required to be added to the initial implantation cost of an institution.

Results and Discussion

Over the study period of 12 years, from the series of 197 patients identified in our database, 161 patients (81.7%) underwent internalization of an SCS system; thus, trial stimulation failed in 36 patients (18.3%) and therefore data in these patients were not included in the analysis. The failure rate of trial stimulation can be directly related to the type of pathological entity being managed,[8] also vary from center to center, and depend on whether the trial stimulation is done at all. For this reason, we have not factored the cost of failed trial stimulation into the overall budgetary calculations, and consequently, this may be considered a limitation of this study. However, we have shown the cost of trial stimulation separately in *Appendix 1*. Individual institutions may like to add this cost to their budget depending on their failure rate and the type of disease being managed. After a mean follow-up period of 43.8 months (3.65 years), 63 adverse events were reported. These complications developed in 51 patients, resulting in 1.23 adverse events per patient (Table 2).

Financial Implications

Implantation Costs. In our institution, the mean cost of implanting an SCS system is $21,595. For US Medicare and BCBS the mean cost was $32,882 and $57,896, respectively *(Appendix 1)*. These prices include the cost of consultation and diagnostic investigations leading up to and including trial stimulation. The cost of a trial stimulation, where internalization is not performed due to the lack of satisfactory pain relief, is $7671 in Canada, $10,900 for US Medicare, and $24,686 for BCBS *(Appendix 1)*. It should be noted that Canada, and our province in particular, is sparsely populated and some patients travel up to 1000 miles to receive specialized pain control therapy. This results in lengthier hospital stays than the US centers may report. For the purpose of these analyses, a Canadian mean length of stay of 3 days (includes hospitalization for trial period) has been used.

TABLE 1: Cost of complications per year over the 12-year study period*

Year	No. of Complications	Mean Total Cost ($)		
		CAD	US MC (USD)	US BCBS (USD)
1995	5	34,385	65,062	144,902
1996	3	10,538	20,081	51,730
1997	4	17,520	34,029	75,838
1998	4	12,554	26,495	61,403
1999	6	37,282	63,034	132,226
2000	4	14,425	29,943	74,319
2001	1	136	382	573
2002	9	44,607	81,355	227,686
2003	6	43,030	78,858	170,718
2004	9	43,400	83,384	192,551
2005	5	16,717	32,636	77,777
2006	7	52,477	91,892	192,384
total	63	327,057	607,875	1,347,564
mean cost/complication		5,191	9,649	21,390
mean cost/complication/patient (total cost/161 patients)		2,031	3,776	8,369
mean cost/complication/patient/FU yr (total cost/161 patients/mean FU of 3.65 yrs)		556	1,034	2,293

* FU = follow-up; MC = Medicare.

Annual Maintenance Costs. The cost of maintaining the device in Canada is $3539. In comparison, an uncomplicated case per year costs $5071 for US Medicare and $7277 for BCBS in the US *(Appendix 1)*. In calculating the maintenance costs, we have amortized the cost of the IPG (nonrechargeable system) and healthcare utilization costs over a 4-year period *(Appendix 1)*. The life of the IPG is estimated to be 4 years, and the device will eventually need to be replaced when the battery becomes depleted. Therefore, one needs to budget for the IPG replacement by amortizing the total cost of the IPG over a 4-year period. This will ensure the funds are available when required.

The life expectancy of an IPG was derived from a thorough scrutiny of the literature. There was scant literature on this subject; we found only 3 relevant papers.[2,3,14] It was decided that the best data would suggest that an IPG has an average lifetime of 49 months.

TABLE 2: Incidence and unit cost per complications*

Complication	Incidence (%)	Cost per Complication ($) CAD	US MC (USD)	US BCBS (USD)
hardware				
displaced electrode requiring op correction	22 (13.6)	3,887	9,141	22,588
fractured electrode	10 (6.2)	6,096	11,386	25,702
hardware malfunction	4 (2.4)	6,436	11,552	22,703
insulation damage	2 (1.2)	4,644	7,830	16,653
discomfort over IPG	4 (2.4)	1,101	1,949	4,845
90° rotation of IPG	2 (1.2)	190	314	801
electrical leak	1 (0.6)	3,005	7,090	14,949
biological				
infection requiring ex- & reimplantation	6 (3.7)	18,837	28,495	54,547
infection not requiring explantation	4 (2.4)	7,144	11,345	28,340
subcutaneous hematoma (aspiration)	8 (4.9)	136	381	573
CSF leak	0	1,026	2,400	7,058

* Between 1995 and 2007, 161 patients underwent implantation of an SCS system. A total of 63 complications occurred in 51 patients.

In their study of 104 patients, Kumar et al.[9] concluded that the mean life expectancy of an IPG was 48 months. In an analysis of 85 patients in whom an SCS was implanted, Van Buyten[24] reported that 61 patients were available for active follow-up and that 32 of these patients had the IPG replaced (mean IPG lifespan 27.9 months). In the remaining 29 patients, the IPG lasted > 5 years. A limitation of that study is that the author only tabulates data for a 5-year period. It was therefore presumed that the remaining 29 patients had IPGs lasting 6 years (72 months) or more. If one takes a mean of these 2 groups, it indicates that the mean life expectancy of the IPG will be 50 months. The third study, by Budd,[3] was excluded from this calculation because of the limited number of patients studied (only 8 of the 20 had an IPG, with a follow-up of only 18 months); this study had no power when using it to interpret battery life.

Rechargeable Systems. With the introduction of rechargeable systems over the last 3–4 years, there is a growing trend toward using these systems; the financial ramification being that the initial implantation costs escalate. It is estimated that the difference between the implantation costs of nonrechargeable and rechargeable systems is approximately $10,591 (CAD) or $10,988 (USD) under Medicare (see Table 4). At the time of writing we were not able to confirm the pricing by BCBS. The higher price tag associated with the implantation of rechargeable systems is chiefly due to the higher cost of the equipment.

The price of the rechargeable system in the US is, at present, in flux. This is due to variable pricing by different manufacturers and is diverse from state to state. The difference in the selling price between the 2 countries is a reflection of the marketing practices. The presumption was made that the professional fees and hospital charges will remain unchanged.

The cost to maintain these systems is likely to fall and will depend predominantly on how long a rechargeable system lasts in reality. At present, the US Food and Drug Administration has approved the system manufactured by Medtronic, Inc. to last for 9 years, Advanced Neuromodulation Systems for 7 years, and Boston Scientific for 5 years. Boston Scientific engineering testing[5] suggests that the battery life of a rechargeable system ranges from 10 to 25 years. The costs associated with annual maintenance and complications will change. We speculate that a person with a rechargeable system will require 2–3 IPG replacements over a lifetime, compared with the 5 or 6 times required for the nonrechargeable system. Variables, such as the age of implantation, development of tolerance, or complications that may require removal of the IPG, will dictate the real cost benefits. At this point, these systems have not been in place long enough to do any long-term cost calculations.

Complication Costs. It is the length of hospitalization, equipment, and the healthcare resources used that drive the cost of complications. The mean cost of a complication was $5191 in Canada, with a range of $136 for aspiration of a subcutaneous hematoma to $18,837 for an infection requiring administration of intravenous antibiotics, explantation of the system, and reimplantation. In comparison, in the US the figures were $9649 (range $381–28,495) for Medicare and $21,390 (range $573–54,547) if covered through BCBS (*Appendix 2*). The costs for each of the complications are displayed in Table 2. The mean complication cost calculations are presented in Table 3.

To the reader it may seem odd that the cost of initial implantation is greater than the cost of an infected system requiring explantation and reimplantation. This is due to the extensive evaluation expenses incurred prior to implantation, such as consultations with multiple healthcare professionals and imaging.

Cost per Patient. In this study, 63 adverse events were reported. These complications developed in 51 patients, resulting in 1.23 adverse events per patient. The mean annual cost of a complication per patient was $556 CAD. Comparatively, in the US the mean cost would be $1034 for Medicare and $2293 for BCBS (Table 3). To provide an example of how these estimates were derived (using CAD values) the total cost of complications ($327,057) was divided by the number of patients whose system was internalized (161) and then divided by the average duration of follow-up (3.65 years) and thus: ($327,057 ÷ 161 patients) ÷ 3.65 years = $556. Although the complication rate and mean annual cost per complication per patient appeared relatively constant, given the relatively low number of complications, this conclusion should be interpreted with some caution. This study highlights that every time an SCS complication occurs, the annual main-

TABLE 3: Summary of cost calculations*

Group	Implantation Costs	Annual Mainte-nance Costs	Mean Cost per Complication†	Annual Cost/ Complication/ Patient‡	Ratio of Cost/ Complication to Annual Mainte-nance Costs§	Budgetary Cap¶
Canada (CAD)	$21,695	$3,539	$5,191	$558	1.4	18.9%
US Medicare (USD)	$32,882	$5,071	$9,649	$1,034	2.0	18.5%
US BCBS (USD)	$57,898	$7,277	$21,390	$2,293	2.9	16.5%
mean						18%

* For budgeting purposes, an implanter needs to calculate the initial cost of implantation of an SCS system for a patient at his or her institution, and then add the budgetary cap of 18% for each new patient undergoing implantation of an SCS system.
† Total cost = $327,057 (CAD), $607,857 (Medicare), and $1,347,564 (BCBS) ÷ total number of complications (63).
‡ Total cost = $327,057 (CAD), $607,857 (Medicare), and $1,347,564 (BCBS) ÷ number of patients treated (161) ÷ mean follow-up period of 3.65 years.
§ The ratio of cost/complication to annual maintenance cost = mean cost/complication ÷ annual maintenance costs.
¶ Budgetary cap: cost of annual maintenance + annual cost/complication/patient ÷ implantation cost × 100 (percentage).

tenance cost increases as follows: 1.4 times in Canada, 2.0 times in US Medicare, and 2.9 times in US BCBS (Table 3).

Financial Impact: Deriving the Formula

To calculate an annual budget, an institution needs to ascertain the amount to be added to the cost of implantation, to allow for the costs associated with annual maintenance, and to resolve potential complications. Taking this into consideration, we have created a formula to calculate the true annual financial impact of SCS per patient implanted in both Canadian and US healthcare systems. The formula is as follows: the annual maintenance cost (a) was added to the average annual cost per complication per patient implanted (b), then divided by the implantation cost (c), and the result was multiplied by 100 to obtain a percentage $(a + b \div c \times 100)$.

Application of this formula, using Canadian cost data, yields a value of 18.9%. In comparison it is 18.5% when using Medicare cost data and 16.5% when using BCBS cost data. To make this budgetary cap universally applicable, we averaged these 3 values and arrived at 18% (Table 3). Because the United Kingdom and European healthcare systems are very similar to the Canadian or US Medicare systems, an 18% grossed-up value would be suitably applicable to them. Therefore, any institution implanting these devices worldwide need only calculate the initial cost of SCS implantation for a patient in that country and add the grossed-up value of 18% for each new patient implanted (118%). For each follow-up patient, only the budgetary cap (18%) will be required.

Conclusions

This study brings to the forefront that complications remain the major contributing factor to the overall expense of SCS. Therefore, it is suggested that facilities that implant SCS systems focus on the various strategies suggested in the literature[4,7,13,14] to reduce the incidence of both biological and hardware-related complications.

To establish a true budget, one must factor in the costs associated with initial implantation, annual maintenance, and complications. Although maintenance costs are relatively stable, it is apparent that every time an SCS complication occurs, the annual maintenance cost increases. Using the calculation we have created, it is suggested that one should allow for a "grossed-up" value of 18%. This amount should be in addition to the implantation costs for the individual institution for new patients, as well as for each actively treated patient. As the initial cost of implantation in any country reflects that country's current economic state, the formula provided to calculate the total budgetary impact of SCS will be universally applicable to all SCS implanters and policy makers alike.

TABLE 4: Difference between country costs associated with nonrechargeable and rechargeable SCS systems

Healthcare System	Professional Fees Only*	Rechargeable Device	Lead†	Rechargeable System	Nonrechargeable System	Difference
Canada (CAD)	8,855	17,550	5,760	32,165	21,564	10,591
US MC (USD)	15,852	20,858	7,160	43,870	32,882	10,988

* Includes trial stimulation.
† Two Octopolar leads.

APPENDIX 1: Total cost and cost breakdown of individual categories*

Cost of Implantation (includes trial stimulation)	CAD	US Medicare (USD)	US BCBS (USD)
consultation			
psychiatrist	147.00	148.06	426.36
social worker	105.00	139.92	345.76
family physician	56.00	121.89	331.08
neurosurgeon	83.40	171.63	411.02
neurologist	123.24	171.63	411.02
orthopedic surgeon	73.50	171.63	411.02
total	588.14	924.76	2,336.26
investigations			
CT scanning (x 1.7)	892.50	728.74	1,860.96
MR imaging (x 1.1)	1,386.00	688.60	2,567.00
radiography (x 5.6)	258.72	301.95	804.78
total	2,537.22	1,719.29	5,232.74
surgery			
anesthesia			
implantation	328.65	652.51	1,684.98
internalization	190.00	349.24	891.46
neurosurgical professional fees			
implantation	673.05	840.53	2,161.87
internalization	233.00	468.55	1,222.99
assistant surgeon	210.00	399.84	1,051.81
total	1,634.70	2,710.67	7,013.11
equipment			
implantable pulse generator (nonrechargeable)			
Synergy	9,995.00	13,290.00	13,290.00
total	9,995.00	13,290.00	13,290.00
electrodes			
Resume/Pisces-Quad	1,995.00	2,240	2,240
in-line connector	750.00	1,500	1,500.00
hospitalization cost (mean 3.0 days)	4,095.00	10,742.00	26,515.70
total	6,840.00	14,482	30,256
total cost of implantation	21,595.06	32,882.46	57,898.41
Maintenance Cost			
family physician (x 4)	224.00	280.32	363.60
neurosurgeon (x 2)	166.80	130.16	161.80
nursing contacts	102.24	186.00	403.00
pharmacotherapy	317.10	603.76	1,591.32
pulse generator amortized over 4 yrs (amortized fee 1/4 of actual)	2,498.75	3,322.50	3,322.50
professional fees for pulse generator change (amortized over 4 years to be considered)			
anesthesia (amortized fee 1/4 of actual)	82.16	191.23	491.93
GP consult (amortized fee 1/4 of actual)	14.00	30.47	82.77
NS consult (amortized fee 1/4 of actual)	20.85	42.75	102.75
NS operating fee (amortized fee 1/4 of actual)	61.16	91.00	182.00
assistant surgeon (amortized fee 1/4 of actual)	26.25	99.96	262.85
hospitalization cost (amortized fee 1/4 of actual)	26.25	113.11	292.38
total maintenance cost per yr	3,639.56	5,071.26	7,277.00
Cost of Trial Stimulation			
consultation			
psychiatrist	147.00	148.06	426.36
social worker	105.00	139.92	345.76
family physician	56.00	121.89	331.08
neurosurgeon	83.40	171.63	411.02
neurologist	123.24	171.63	411.02
orthopedic surgeon	73.50	171.63	411.02
neuromodulation nurse	329.80	600.00	1,300.00
total	917.94	1,524.76	3,636.26
investigations			
CT scanning (x 1.7)	892.50	728.74	1,860.96
MR imaging (x 1.1)	1,386.00	688.60	2,567.00
radiography (x 5.6)	258.72	301.95	804.78
total	2,537.22	1,719.29	5,232.74
surgery			
anesthesia			
implantation	328.65	652.51	1,684.98
neurosurgical professional fees			
implantation	673.05	840.53	2,161.87

(continued)

APPENDIX 1: Total cost and cost breakdown of individual categories* *(continued)*

	CAD	US Medicare (USD)	US BCBS (USD)
removal of failed system	183.75	343.00	891.80
total	856.80	1,836.04	4,736.65
electrodes			
Resume/Pisces-Quad	1,995.00	2,240.00	2,240.00
hospitalization cost (mean 1.0 day)	1,365.00	3,580.00	8,838.60
total cost of trial stimulation	7,671.96	10,900.09	21,688.25
Cost of Explantation for Poorly Functioning System			
hospitalization cost (mean 1.0 day)	1,365.00	3,580.90	8,838.60
thoracic & lumbar radiography			
technical (x 2)	63.00	77.42	202.11
professional (x 2)	30.24	34.00	84.60
family physician initial visit	58.00	121.89	331.08
NS initial consultation	83.40	171.63	411.02
surgeons fees	183.75	890.56	1,940.84
family physician follow-up visit	28.00	65.08	90.90
neurosurgical follow-up visit	42.00	65.08	90.90
drugs	53.13	95.63	241.74
total	1,904.52	5,102.19	12,231.79

* Abbreviations: GP = general practitioner; NS = neurosurgery.

APPENDIX 2: Total cost and cost breakdown of individual complications*

Hardware-Related Complications	CAD	US Medicare (USD)	US BCBS (USD)
displaced electrode			
hospitalization cost (mean 2.0 days)	2,730.00	7,161.80	17,677.20
thoracic & lumbar radiography			
technical (x 2)	63.00	77.42	202.11
professional (x 2)	30.24	34.00	85.00
family physician initial visit	56.00	121.89	331.08
NS initial consultation	83.40	171.63	411.02
surgeon fee	311.85	407.59	1,081.00
anesthesia fee (1.5 hrs)	380.10	740.45	1,925.17
family physician follow-up visit	28.00	65.08	90.90
NS follow-up visit	42.00	65.08	90.90
neuromodulation nurse (x 3 hrs)	98.94	180.00	390.00
drugs	63.63	117.00	304.20
total	3,887.16	9,141.94	22,688.58
fractured electrode			
hospitalization cost (mean 2.0 days)	2,730.00	7,160.00	17,677.20
thoracic & lumbar radiography			
technical (x 2)	63.00	77.42	202.11
professional (x 2)	30.24	34.00	84.60
family physician initial visit	58.00	121.89	331.08
NS initial consultation	83.40	171.63	411.02
cost of replacement electrode	1,995.00	2,240.00	2,240.00
surgeon fee	771.00	407.59	1,940.84
anesthesia fee (1.75 hrs)	135.00	740.46	1,925.17
family physician follow-up visit	28.00	65.08	90.90
NS follow-up visit	42.00	65.08	90.90
neuromodulation nurse (x 3 hrs)	98.94	180.00	390.00
drugs	63.63	122.85	317.89
total	6,098.21	11,385.99	25,701.71
hardware malfunction requiring replacement			
hospitalization cost (mean 1.5 days)	2,047.50	6,371.35	13,257.90
thoracic & lumbar radiography			
technical (x 2)	63.00	77.42	202.11
professional (x 2)	30.24	34.00	84.60

(continued)

APPENDIX 2: Total cost and cost breakdown of individual complications* *(continued)*

Hardware-Related Complications	CAD	US Medicare (USD)	US BCBS (USD)
family physician initial visit	56.00	121.89	331.08
NS initial consultation	83.40	171.63	411.02
cost of replacement electrode	1,995.00	2,240.00	2,240.00
cost of replacement connector cord	750.00	1,500.00	1,500.00
surgeons fee (replace electrode)	771.00	890.56	1,940.84
anesthesia fee (1.75 hrs)	417.38	739.08	1,921.62
family physician follow-up visit	28.00	65.08	90.90
NS follow-up visit	42.00	65.08	90.90
neuromodulation nurse (x 3 hrs)	98.94	180.00	390.00
drugs	63.13	95.63	241.74
total	6,435.59	11,651.72	22,702.71
electrical leak			
hospitalization cost (mean 1.0 days)	1,365.00	3,580.90	8,838.60
thoracic & lumbar radiography			
technical (x 2)	63.00	77.42	202.11
professional (x 2)	30.24	34.00	84.60
family physician initial visit	56.00	121.89	331.08
NS initial consultation	83.40	171.63	411.02
replacement connector cord	750.00	1,500.00	1,500.00
surgeon fees (to replace connector cord)	244.85	890.56	1,940.84
anesthesia fee (1 hr)	190.00	314.21	801.39
family physician follow-up visit	28.00	65.08	90.90
NS follow-up visit	42.00	65.08	90.90
neuromodulation nurse (x 3 hrs)	98.94	180.00	390.00
drugs	54.23	94.91	267.77
total	3,005.46	7,095.68	14,949.21
discomfort over IPG requiring repositioning			
day-surgery charge	330.75	578.56	1,504.27
family physician initial visit	56.00	121.89	331.08
NS initial consultation	83.40	171.63	411.02
surgeon's fee (IPG repositioning)	244.85	407.59	1,081.00
anesthesia fee (1 hr)	190.00	314.21	801.39

(continued)

APPENDIX 2: Total cost and cost breakdown of individual complications* *(continued)*

Hardware-Related Complications	CAD	US Medicare (USD)	US BCBS (USD)
family physician follow-up visit	28.00	65.08	90.90
NS follow-up visit	42.00	65.08	90.90
neuromodulation nurse (x 2 hrs)	65.96	120.00	260.00
drugs	60.48	105.84	275.18
total	1,101.24	1,949.08	4,845.74
insulation damage to the use of twist lock anchor			
hospitalization cost (mean 1.0 day)	1,365.00	3,580.90	8,830.60
thoracic & lumbar radiography			
technical (x 2)	63.00	77.42	202.11
professional (x 2)	30.24	34.00	84.80
family physician initial visit	56.00	121.89	331.08
NS initial consultation	83.40	171.63	411.02
replacement lead	1,995.00	2,240.00	2,240.00
surgeon fee (replacement of lead)	641.00	890.56	1,940.84
anesthesia fee (1 hr)	190.00	314.21	801.39
family physician follow-up visit	28.00	65.08	90.90
NS follow-up visit	42.00	65.08	90.90
neuromodulation nurse (x 3 hrs)	98.94	180.00	390.00
drugs	50.96	89.18	231.86
total	4,643.54	7,829.95	15,653.30
90° rotation of IPG			
surgeon fee	0.00	0.00	0.00
hospitalization cost (0 days)	0.00	0.00	0.00
anesthesia fee (1 hr)	190.00	314.21	801.39
drugs	0.00	0.00	0.00
neuromodulation nurse	0.00	0.00	0.00
total	190.00	314.21	801.39
infection not requiring explantation			
hospitalization cost (mean 1.5 days)	2,730.00	5,371.35	13,257.90
laboratory expenses: blood work & cultures	68.25	135.30	363.79
infectious disease consultation	117.07	171.63	411.02
family physician initial visit	56.00	121.89	331.08

(continued)

APPENDIX 2: Total cost and cost breakdown of individual complications* *(continued)*

Biologically Related Complications	CAD	US Medicare (USD)	US BCBS (USD)
NS initial consultation	83.40	171.63	441.02
family physician follow-up visit (x 2)	56.00	130.16	181.80
neurosurgical follow-up visit (x 2)	82.00	130.16	181.80
neuromodulation nurse to monitor infection (x 3 hrs)	98.94	180.00	390.00
drugs: IV antibiotic therapy at home	944.62	1,574.37	4,093.36
home care nurse visit (x 2 visits/day x 42 days)	2,770.32	3,108.00	8,080.80
infectious disease follow-up	53.97	93.00	213.94
other drugs	83.44	167.42	394.30
total	7,114.01	11,344.91	28,340.81
infection requiring explantation & reimplantation			
hospitalization cost (mean 2.6 days)	3,649	9,310.34	22,980.36
laboratory expenses: blood work & cultures	68.25	135.30	363.79
infectious disease consultation	117.07	171.63	441.02
family physician initial visit	56.00	121.89	331.08
NS initial consultation	83.40	171.63	411.02
surgeon fee (explantation of electrode)	183.75	450.09	1,130.90
surgeon fee (reimplantation of electrode and IPG)	874	420.42	1,133.33
anesthesia fee (1 hr for explantation)	190	326.18	824.73
anesthesia fee (2 hrs for reimplantation)	350	597.05	1,468.87
family physician follow-up visit (x 4)	112	260.32	363.60
NS follow-up visit (x 3)	126.00	195.24	272.69
neuromodulation nurse supervision (x 4 hrs)	131.92	240.00	520.00
neuromodulation nurse for programming (x 3 hrs)	98.94	180.00	390.00
drugs: IV antibiotic therapy at home	944.62	1,574.37	4,093.36
home care nurse visit (x 2 visits/day x 42 days)	2,770.32	3,108.00	8,080.80
cost of replacement electrode	1,995.00	2,240.00	2,240.00
cost of replacement IPG	8,995.00	8,645.00	8,645.00

(continued)

APPENDIX 2: Total cost and cost breakdown of individual complications* *(continued)*

Biologically Related Complications	CAD	US Medicare (USD)	US BCBS (USD)
infectious disease follow-up (x 2)	107.94	186.00	427.88
other drugs	83.44	161.27	431.60
total	18,837	28,294.73	64,547.93
subcutaneous hematoma requiring surgical evacuation			
added cost in addition to primary procedure			
surgeon fee for evacuation	174.30	407.38	1,059.19
anesthesia fee (1/2 hr)	120.00	196.00	509.60
ambulatory care tray service	99.75	166.25	166.25
total	394.05	769.63	1,735.04
subcutaneous hematoma requiring aspiration only			
added cost in addition to primary procedure			
aspiration of hematoma	36.75	207.19	383.30
ambulatory care tray service	99.75	174.56	190.10
total	136.50	381.76	573.40
CSF leakage due to accidental dural puncture during implantation			
fluoroscopy suite	236.25	467.46	1,202.78
surgeon fee	210.00	407.59	1,940.84
anesthesia fee (1 hr)	190.00	784.95	1,967.72
recovery room charges	199.50	391.39	1,012.78
blood patch	157.50	308.70	804.18
neuromodulation nurse (x 1 hr)	32.98	60	130.00
total	1,026.23	2,400.09	7,058.28

* IV = intravenous.

Disclaimer

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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Recent Average Price Trends for Implantable Medical Devices, 2007-2011

September 2013

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Introduction and Summary of Findings

In this study, we examine empirical evidence on reported average price trends for several major categories of implantable medical devices (IMDs) over the period 2007 through 2011.

We find that the reported average price for each type of implantable medical device studied declined during this period, both on a nominal and inflation-adjusted basis. Using the medical care CPI, we calculate the decline in inflation-adjusted prices to be from 17 to 34 percent depending on the device category.

Study Scope and Approach

This study provides recent evidence on trends in reported average selling prices paid for selected categories of IMDs among a sample of up to 294 hospitals for the period 2007 to 2011.

Average pricing data for selected device categories

Average pricing data were obtained from Millennium Research Group, Inc. (MRG), an independent third-party provider of proprietary survey data of average selling prices, for the following seven categories of medical devices:

- cardiac resynchronization therapy defibrillators (CRTDs);
- implantable cardioverter defibrillators (ICDs);
- pacemakers;
- artificial hips;
- artificial knees;
- drug eluting stents; and
- bare metal stents.

The survey included results from 153 to 294 hospitals (depending on the device category and year). The hospital sample is characterized by MRG as nationally representative in terms of the mix of hospital characteristics and geography. The average pricing data are described as

[1] Contact information: glong@analysisgroup.com.

[2] This research was supported by the Advanced Medical Technology Association. The design, analysis, and composition of the analyses presented were conducted independently and entirely by the authors, and we are responsible for any errors or misstatements. The authors thank Millennium Research Group, Inc. for survey data on average selling prices for the selected implantable medical device categories.

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reflecting net acquisition costs reported by hospitals after accounting for all discounts and rebates.

The pricing data presented summarize *average* prices reported by the sample of hospitals for all models and manufacturers in a given device category, rather than trends for any specific model of device or manufacturer. The reported average prices are sales-weighted across all manufacturers and types of devices (e.g., dual chamber pacemakers vs. single chamber pacemakers) within each selected category for the surveyed hospitals. As a result, factors other than pricing at the specific product level may affect changes in the reported average prices paid over time (either within a given hospital, or over all hospital survey respondents), such as:

- Changes in *product mix* within a given device category over time.

In addition, the reported average selling price reflects trends in the average price of the given device type, rather than trends in the overall, or medical device-related costs to the hospital for a given patient procedure. Factors other than the reported average selling price of the device type may affect hospital device-related costs for a patient procedure, including:

- Changes in the average *intensity of use* per patient procedure over time (e.g., the average number of stents used per patient procedure);
- Changes in the *quality and features* of the products over time (which might be correlated with average prices, and might also lead to corresponding changes in patient outcomes, costs, treatment setting, or other metrics).

To the extent that the device types examined have increased in quality over time and offer improved patient outcomes, the average reported price trends may understate the decline in quality-adjusted real prices. Such developments were outside the scope of our review.

Inflation adjusted prices

To compare expenditure figures on a common basis, all prices were inflated to 2011 real values using the Consumer Price Index for all urban consumers for medical care expenditures (medical care CPI).[3] The medical care CPI measures inflation for a market basket of medical care products and services, holding quality and quantity of the products and services constant. Trends in the average reported selling price for selected IMDs adjusting for inflation using the medical care CPI may therefore be compared relative to the trend in the average price of medical care products and service generally. For example, a decline in the reported real average selling price for an IMD would mean that the average cost for devices of that type declined by more than the cost of other medical care items. A sensitivity analysis was conducted using the general CPI for all urban consumers (the CPI-U) and results are presented in Appendix A.[4] Price trends for the nominal reported average prices prior to inflation adjustments are presented in Appendix B.

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[3] Bureau of Labor Statistics, Consumer Price Index -- All Urban Consumers, Medical Care, Accessed December 20, 2012, from http://data.bls.gov/pdq/querytool.jsp?survey=cu.

[4] Results in Appendix A reflect trends in the reported average prices of IMDs relative to average prices in the economy generally. Results are largely consistent regardless of whether the inflation adjustment is implemented using the medical care CPI or the general CPI for all urban consumers.

Finding: Reported average prices paid for the medical devices reviewed declined from 2007 to 2011 on an inflation-adjusted basis

Reported average device prices declined in each device category over the period 2007 to 2011, on both a real (inflation-adjusted) and nominal basis. Table 1 reports the change in the average selling price for each category of device relative to the 2007 average price and after adjusting for inflation.[5] Figure 1 presents a corresponding graphical representation. The average selling price for each device category declined in real terms between 2007 and 2011. The size of this decline ranges from a 17 percent decline for artificial knees to a 34 percent decline for drug eluting stents (corresponding to an average annual rate of decline of -4.6 percent and -10.5 percent, respectively).

Table 1
Percentage Change in Reported Average Real Prices by Medical Device Category[6]
2007 to 2011

In Real 2011 Dollars (Adjusted by medical care CPI)

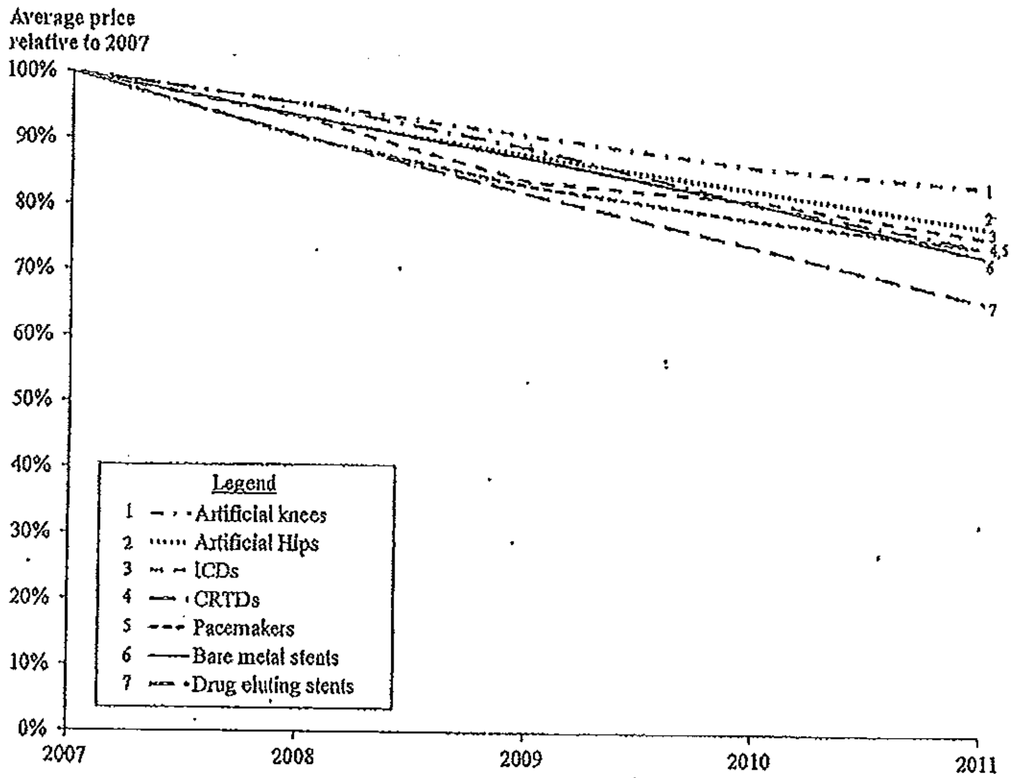
Device category	2007	2008	2009	2010	2011	Total Percentage change
CRTDs	100%	95%	89%	80%	74%	-26%
ICDs	100%	93%	84%	81%	76%	-24%
Pacemakers	100%	90%	83%	78%	74%	-26%
Artificial hips	100%	93%	88%	83%	77%	-23%
Artificial knees	100%	95%	91%	86%	83%	-17%
Drug eluting stents	100%	90%	82%	74%	66%	-34%
Bare metal stents	100%	93%	87%	80%	73%	-27%

Notes: The device category "Artificial hips" reflects a total hip replacement and is calculated as the sum of the average prices for acetabular liners, acetabular shells femoral heads, and femoral stems. The device category "Artificial knees" reflects a total knee replacement and is calculated as the sum of the average prices for bicondylar femoral components, patella, tibial insert, and tibial tray. Inflation adjusted using the medical care CPI.

[5] Table 1 utilizes the medical care CPI. Appendix A includes this analysis adjusted by the CPI-U.
[6] Average price data provided by Millennium Research Group, Inc. (©2012 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.). Medical care CPI data accessed from the Bureau of Labor Statistics.

Figure 1
Percent Change in Reported Average Real Prices by Medical Device Category[7]
2007 to 2011

In Real 2011 Dollars (Adjusted by medical care CPI)



Data Interpretation

The price trends presented reflect the average reported price paid of the device component examined, as opposed to the average total medical device-related costs for a procedure involving that device.

- The average device price does not reflect changes in the *intensity of use* of the device per patient procedure over time (e.g. any changes in the number of studied devices implanted during a single procedure).

[7] Average price data provided by Millennium Research Group, Inc. (©2012 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.). Medical care CPI data accessed from the Bureau of Labor Statistics.

- The average device price reflects changes in *product mix* over time (e.g., as a result of substituting less or more expensive models of devices in the same category as a result of technological advances or purchasing initiatives), rather than the price for a given device from a given manufacturer over time, which may have increased or decreased.
- The average device price does not capture changes in the average *quality or features* of devices in the category over time (or the resulting implications for hospital non-device costs, such as the length of stay or utilization of other resources, or on patient outcomes).

<u>Conclusion</u>

Assuming that the reported pricing data are generally representative of U.S. hospitals and their prices paid, the findings suggest that average prices for implantable medical devices paid by hospitals have declined substantially in recent years on an inflation-adjusted basis.

Appendix A
Trends in Reported Average Device Price
CPI-U Inflation-Adjusted

Table A1 reports the results contained in Table 1, but applies the general CPI-U rather than the medical care CPI to adjust reported IMD average prices.[8]

In general, the CPI-U reflects a slightly lower level of inflation compared to the medical care CPI; however, the findings are generally consistent regardless of whether the inflation adjustment relies on the medical care CPI or the general CPI-U. Reported average price declines are observed for all studied categories of IMDs.

Table A1
Percentage Change in Reported Average Real Prices by Medical Device Category[9]
2007 to 2011

In Real 2011 Dollars (Adjusted by CPI-U)

Device category	2007	2008	2009	2010	2011	Total Percentage change
CRTDs	100%	95%	92%	85%	78%	-22%
ICDs	100%	93%	86%	85%	79%	-21%
Pacemakers	100%	90%	86%	82%	78%	-22%
Artificial hips	100%	93%	91%	87%	81%	-19%
Artificial knees	100%	95%	94%	90%	87%	-13%
Drug eluting stents	100%	90%	85%	78%	69%	-31%
Bare metal stents	100%	93%	90%	85%	76%	-24%

Notes: The device category "Artificial hips" reflects a total hip replacement and is calculated as the sum of the average prices for acetabular liners, acetabular shells femoral heads, and femoral stems. The device category "Artificial knees" reflects a total knee replacement and is calculated as the sum of the average prices for bicondylar femoral components, patella, tibial insert, and tibial tray. Inflation adjusted using the general CPI-U.

[8] Bureau of Labor Statistics, Consumer Price Index – All Urban Consumer, All Items, Accessed December 20, 2012, from http://data.bls.gov/pdq/querytool.jsp?survey=cu.

[9] Average price data provided by Millennium Research Group, Inc. (©2012 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.). CPI-U data accessed from the Bureau of Labor Statistics.

Appendix B
Trends in Reported Average Device Price
Nominal Prices

Table B1 reports the results contained in Table 1, but reports the nominal reported IMD average prices prior to any inflation adjustment. Reported average nominal price declines are observed for all categories of IMDs examined.

Table B1
Percentage Change in Reported Average Nominal Prices by Medical Device Category[10]
2007 to 2011

In Nominal Dollars (Not Inflation Adjusted)

Device category	2007	2008	2009	2010	2011	Total Percentage change
CRTDs	100%	99%	95%	89%	84%	-16%
ICDs	100%	97%	89%	90%	86%	-14%
Pacemakers	100%	94%	89%	86%	84%	-16%
Artificial hips	100%	97%	94%	91%	88%	-12%
Artificial knees	100%	99%	97%	95%	95%	-5%
Drug eluting stents	100%	94%	87%	82%	75%	-25%
Bare metal stents	100%	97%	93%	89%	83%	-17%

Notes: The device category "Artificial hips" reflects a total hip replacement and is calculated as the sum of the average prices for acetabular liners, acetabular shells femoral heads, and femoral stems. The device category "Artificial knees" reflects a total knee replacement and is calculated as the sum of the average prices for bicondylar femoral components, patella, tibial insert, and tibial tray.

[10] Average price data provided by Millennium Research Group, Inc. (©2012 Millennium Research Group, Inc. All rights reserved. Reproduction, distribution, transmission or publication is prohibited. Reprinted with permission.).